



Astellas Pharma US, Inc.

VIBATIV® (telavancin for injection) – Critical shortage

December 2, 2011

Dear Healthcare Professional:

This communication is a follow up to our initial communication dated November 16, 2011 advising you of an issue that has occurred at the third party manufacturer of VIBATIV. The manufacturer has informed Astellas that they have notified the United States Food and Drug Administration of an ongoing investigation related to their production equipment and processes. The notification includes all products manufactured at their facility which remain within expiry, including current batches of VIBATIV.

Based on this information and our ongoing commitment to patient safety, Astellas Pharma US, Inc. has decided to voluntarily place a hold on distribution of VIBATIV to wholesalers. As a result, there is a critical shortage of VIBATIV.

The duration of the distribution hold is difficult to predict and has now resulted in critical product shortages and regional supply outages. **While Astellas is not withdrawing the product from the market, we recommend that patients not be initiated on VIBATIV therapy unless sufficient supply is available at your institution.**

Astellas is not aware of any adverse reactions or safety issues with the use of VIBATIV related to manufacturing concerns. We will continue to carefully evaluate the situation and inform you as new information becomes available.

Adverse reactions or quality problems experienced with the use of this product may be reported to Astellas Pharma US, Inc. at 1-800-727-7003 or FDA at

Astellas Pharma US, Inc.

Three Parkway North, Deerfield, IL 60015-2537
Tel: 1-800-888-7704 Fax: 1-800-688-6668

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1-800-FDA-1088 or www.fda.gov/medwatch.

We are committed to resolving this issue and will continue to provide you with updates as new information becomes available. For information on the use of VIBATIV, please read the full U.S. prescribing information at www.vibativ.com/PrescribingInformation.aspx or contact Astellas Medical Information at 1-800-727-7003.

Sincerely,

M. Joyce Rico, MD
Vice President, Medical Affairs
Astellas Pharma Global Development, Inc.

Astellas Pharma US, Inc.

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